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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,414	02/27/2004	Brian M. Aquila	SPV-047.02	5245
25181	7590	12/22/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,414

Applicant(s)

AQUILA ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,20,39 and 58 is/are rejected.
- 7) ☒ Claim(s) 1-6, 8-10, 13-17,19-25, 27-29,32-36, 38-44, 46-48,51-55,57-63, 65-67, 70-74 and 76 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/27/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Continuation of Disposition of Claims: Claims pending in the application are 1-6,8-10,13-17,19-25,27-29,32-36,38-44,46-48,51-55,57-63,65-67,70-74 and 76.

DETAILED ACTION

This application is a divisional of US 10/012242. the restriction made in the parent is given below:-

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-8,20,22-27,39,44,46,58,60-63,65, drawn to compounds of formula I-IV wherein n is 0 and Z is NHR", classified in class 548, subclass 566.
- II. Claims 1, 3-7,20, 22-26,39, 41-45,58,60-64, drawn to compounds of formula I-IV wherein n is 0 and Z is an OH, classified in class 548, subclass 570.
- III. Claims 1-6,8-10, 13-17,19-25, 27-29,32-36,38-44,46-48,51-55,57-63,65-67,70-74,76, drawn to compounds of formula I-IV wherein n is 1 and Z is NHR", classified in class 546, subclass 246.
- IV. Claims 1-7, 9-12, 15-18, 20-26, 28-31,34-45,47-50,53-56, 58-64,66-69,72-75, drawn to compounds of formula I-IV wherein n is 1 and Z is OH, classified in class 546, subclass 248.
- V. Claims 1, 3-8,20,22-27,39,41-46,58,60-65, drawn to compounds of formula I-IV wherein n is 2 and Z is NHR" or OH classified in class 540, subclass 609.
- VI. Claims 77-104, drawn to a process of making cyclic compounds classified in various classes and subclasses.

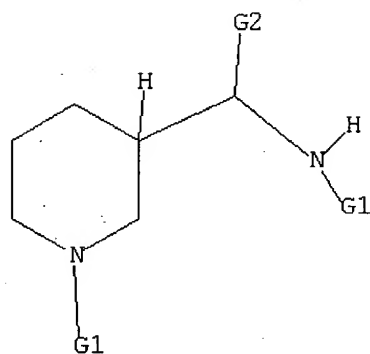
Applicants have elected group III wherein n is 1 and Z is NHR".

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Applicants have cancelled claims 7,11,12, 18,26,30,31,37,45, 49, 50, 56, 64, 68,69,75 and 77-104 without prejudice.

Claims pending are 1-6, 8-10, 13-17,19-25, 27-29,32-36, 38-44, 46-48,51-55,57-63, 65-67, 70-74 and 76.

Upon doing the generic search for group III, it did not run to completion and there were several iterations see below



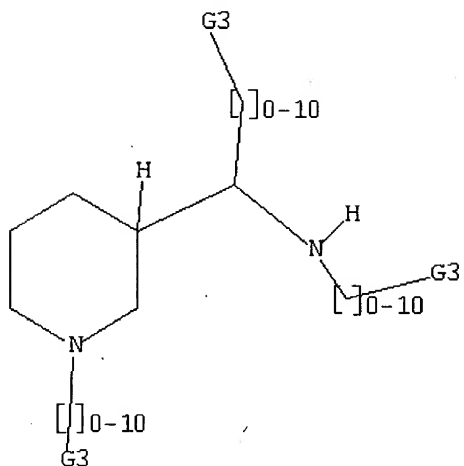
G1 H, Ak, Cb

G2 Cb, Ak

5.0% PROCESSED 1000 ITERATIONS
INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)
SEARCH TIME: 00.00.01

FULL FILE PROJECTIONS: ONLINE **INCOMPLETE**
BATCH **COMPLETE**
PROJECTED ITERATIONS: 394031 TO 411009

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0.5% PROCESSED 1000 ITERATIONS
 INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)
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FULL FILE PROJECTIONS: ONLINE **INCOMPLETE**
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and hence the examiner **further restricted** group III to

Group IIIa drawn to compounds wherein n is 1, Z is NHR'', R is alkyl aryl, R' is an alkyl and R'' is an aryl.

Group III b drawn to compounds wherein n is 1, Z is NHR'', and R, R' and R'' are of a different combination than given in group IIIa. A further election of a single disclosed species is required.

During a telephone conversation with Dr. Dana Gordon on 12/20/04 a provisional election was made with traverse to prosecute the invention of Group IIIa, claims 1-6, 8-10, 13-17, 19-25, 27-29, 32-36, 38-44, 46-48, 51-55, 57-63, 65-67, 70-74 and 76 wherein n is 1, Z is NHR'', R is alkyl aryl, R' is an alkyl and R'' is an aryl.

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Affirmation of this election must be made by applicant in replying to this Office action.

Claim 1, 20, 39 and 58 all in part are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 20, 39 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for aryl to be phenyl, does not reasonably provide enablement for any and all the aryls. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or

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use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims is very large. Applicants definition of an aryl is confusing since the heterocyclic and hetero aromatics have been further defined are the ones with hetero atoms.

The guidance provided by the applicants are drawn to compounds wherein aryl is a phenyl group.

The process of making compounds would depend upon the type of group hetero or non-hetero present on the N of the piperidine.

Thus applicants have not provided clear guidance and direction since there are no working examples.

Applicants can overcome this by limiting the aryl to phenyl.

Conclusion

Close Prior Art:-

US 6645980, USW 6677332, 6635661 Cuny et al teaches similar compounds but the N-Boc derivative. Not the N-alkyl aryl. Also compounds such as 211 and 212 which have the N-alkyl aryl but then the R1 is a H.

The claims 1-6, 8-10, 13-17, 19-25, 27-29, 32-36, 38-44, 46-48, 51-55, 57-63, 65-67, 70-74 and 76 wherein n is 1, Z is NHR'', R is alkylaryl (alkylphenyl), R' is an alkyl and R'' is an aryl (phenyl) are found to be allowable over the prior art of record.

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If applicants amend the claims to the elected group and also overcome the 112 issues the claims will be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.D.
December 20, 2004

Rita J. Desai
Primary Examiner
Art Unit 1625
RJ Desai
12/20/04